

22 FEB 2005

PCT

From the INTERNATIONAL BUREAU

**NOTIFICATION CONCERNING  
SUBMISSION OR TRANSMITTAL  
OF PRIORITY DOCUMENT**

(PCT Administrative Instructions, Section 411)

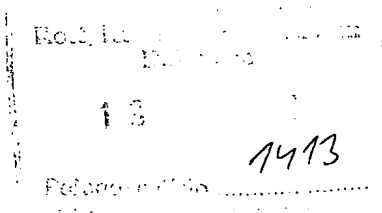
To:

JIROTKOVA, Ivana  
Rott, Ruzicka & Guttman  
Patent, Trademark & Law Office  
Nad Stolou 12  
P.O. Box 94  
170 00 Praha 7  
Czech Republic

Date of mailing (day/month/year) 07 November 2003 (07.11.03)	
Applicant's or agent's file reference PV/395/PCT	<b>IMPORTANT NOTIFICATION</b>
International application No. PCT/CZ03/00049	International filing date (day/month/year) 26 August 2003 (26.08.03)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 27 August 2002 (27.08.02)
Applicant LECIVA, a.s. et al	

- The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
- An asterisk(\*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
27 Augu 2002 (27.08.02)	pv 2002-2906	CZ	02 Sept 2003 (02.09.03)



<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. (41-22) 338.71.40</p>	<p>Authorized officer</p> <p>Olivia TEFY</p> <p>Telephone No. (41-22) 338 8516</p>
-----------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------

# PATENT COOPERATION TREATY

<b>Att. Ruzicka &amp; Guttman</b> Došlo dne <div style="font-size: 1.2em; font-weight: bold;">22.11.2004</div> Pořadové číslo .....
----------------------------------------------------------------------------------------------------------------------------------------------

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Jirotkova, Ivana  
ROTT, RUZICKA & GUTTMANN  
Patent, Trademark & Law Office  
Nad Stolou 12  
P.O. Box 94  
170 00 Praha 7  
REPUBLIQUE TCHEQUE

**NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**  
(PCT Rule 71.1)

Date of mailing (day/month/year)	18.11.2004
-------------------------------------	------------

Applicant's or agent's file reference PV/395/PCT	<b>IMPORTANT NOTIFICATION</b>
-----------------------------------------------------	-------------------------------

International application No. PCT/CZ 03/00049	International filing date (day/month/year) 26.08.2003	Priority date (day/month/year) 27.08.2002
--------------------------------------------------	----------------------------------------------------------	----------------------------------------------

Applicant ZENTIVA, A.S. et al.
-----------------------------------

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

**4. REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.


Name and mailing address of the international preliminary examining authority:	Authorized Officer
--------------------------------------------------------------------------------	--------------------

European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Ullrich, J Tel. +49 89 2399-8048
---------------------------------------------------------------------------------------------------------------	-------------------------------------



## PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PV/395/PCT	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/CZ 03/00049	International filing date ( <i>day/month/year</i> ) 26.08.2003	Priority date ( <i>day/month/year</i> ) 27.08.2002
International Patent Classification (IPC) or both national classification and IPC C07D495/04		
Applicant ZENTIVA, A.S. et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand  08.03.2004	Date of completion of this report  18.11.2004	
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Schmid, A  Telephone No. +49 89 2399-8591	



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/CZ 03/00049**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-7 as originally filed

**Claims, Numbers**

1-7 as originally filed

**Drawings, Sheets**

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/CZ 03/00049

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-6
	No: Claims	7
Inventive step (IS)	Yes: Claims	1-6
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-7
	No: Claims	

2. Citations and explanations

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

---

International application No. PCT/CZ 03/00049

**Re Item V**

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1) US-A-6,429,210 (D1) discloses in figures 1-4 the x-ray and infrared spectra of the form 1 of clopidogrel hydrogen sulfate which has been previously prepared in US-A-4,847,265 (cf. also D1, col. 1, lines 26-38).

The applicant has claimed the form 1 in claim 7 by a product-by-process formulation. However, the characterisation of a product does not render the product novel if it is known per se from the prior art (cf. above).

Accordingly the subject-matter of present claim 7 is not novel with regard Article 33(2) PCT.

- 2) The present preparation method differs from the ones known from D2 and especially D1 in the use of a solvent chosen from lower alcohols and their esters with lower acids whereas D1 precipitates the clopidogrel hydrogen sulfate out of acetone thereby obtaining the thermodynamically stable form II.

Therefore the subject-matter of present claims 1-6 is novel pursuant to Article 33(2) PCT.

Since it was not predictable from D1 that such a change in the process would lead to a reliable method (cf. present examples) of obtaining form I of clopidogrel hydrogen sulfate in a high yield also an inventive step according to Article 33(3) PCT can be acknowledged for present claims 1-6.